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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/797,770	02/07/1997	ANDREW D. BAROFSKY	4430-18	1692

20575 7590 01/23/2002

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EXAMINER

PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 01/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/797,770

Applicant(s)

BAROFSKY ET AL

Examiner

Paul B. Prebilic

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 15-24, 36-39, 41-55, 74 and 76-104 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 15-24, 36-39, 41-55, 74 and 76-104 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Claim Rejections - 35 USC ' 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24, 36-39, 41-55, 74, 76-98, and 100-104 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to 24, 36-39, 41-55, 74, 76-98, and 100-104, the terminology of "consisting essentially of" has a confusing and indefinite scope in that it apparently does not preclude crosslinking agents used to polymerize the tropoelastin (see page 8, line 21 to page 9, line 9 of the present specification), but it does, according the Applicant's argument, preclude fibrin and polypeptides; see the 37 CFR 1.132 declaration filed July 12, 1999. Applicant argues that crosslinking agents are precluded also; see page 16, lines 20-22 of the amendment filed February 26, 2001. It is the Examiner's position that crosslinking agents, fibrin, and polypeptides are all material to the structure and that they would be precluded by "consisting essentially of" language. Indeed, the use of this terminology is inconsistent with the specification and does not have clear definite basis therefrom. In view of the Applicant's specification, however, this terminology will be interpreted as having the same scope as "comprising" because this is the broadest reasonable interpretation.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

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and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.3218 may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-13, 15, 21, 22, 24, 74, 76-90, and 95-100 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16-33 of copending Application No. 09/000,604. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claim sets parallel each other in that the present claims set forth a biomaterial and the copending claims set forth an elastin biomaterial. However, since "biomaterial" is a broader more generic term than "elastin biomaterial" is, the Examiner posits that the present and patented claim sets are obvious in view of each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections Based Upon Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 3718 of this title before the invention thereof by the applicant for patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-13, 15-24, 36-39, 41-55, 74, 76-100, and 103-104 are rejected under 35 U.S.C. 102(a) as anticipated by Gregory et al (WO 96/14807) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gregory et al (WO 96/14807) in view of Labroo et al (US 5,428,014). Gregory et al is viewed as anticipating the present claims because crosslinked or polymerized tropoelastin is elastin even though it is not called such in the disclosure because the tropoelastin is uncrosslinked and unpolymerized precursor to elastin (i.e. this is definition of tropoelastin in the present specification); see the entire disclosure of Gregory et al, especially Figure 1, page 1, lines 12-23 and page 8, line 21 to page 9, line 9. In other words, tropoelastin monomer is merely a precursor to elastin such that when tropoelastin is formed into a biomaterial by crosslinking or polymerization, it becomes elastin. Therefore, the term tropoelastin biomaterial, as defined in the present specification as crosslinked or polymerized tropoelastin, is actually elastin or elastin-based material. For these reasons, the claims are anticipated by Gregory et al (WO).

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Alternatively, one may not consider the claims anticipated by Gregory et al because tropoelastin is not explicitly stated therein. However, the Examiner posits that it would have been obvious to use tropoelastin as the elastin-like material of Gregory et al because it is so similar to elastin in tissue binding properties that it is considered interchangeable therewith; see Labroo et al on Col. 9, lines 1-26. Furthermore, it is prima facie obvious to use tropoelastin in the Gregory et al invention because it is an elastin-based material as required by Gregory et al.

Claims 47 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Applicant's Admission wherein the claimed process of tropoelastin polymerization reads on the natural process of elastin formation in vertebrates according to Bedell-Hogan, et al in the Journal of Biological Chemistry; see page 1, lines 12-23 of the present specification.

Claims 47, 48, and 53-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Labroo et al (US 5,428,014) wherein the terminology "consisting essentially of" does not apparently preclude crosslinking agents to polymerize tropoelastin. Therefore, "consisting essentially of" does not necessarily eliminate other polypeptides as disclosed by Labroo et al because these other polypeptides could be construed as crosslinking agents; see the whole document especially Col. 9, lines 1-21.

Allowable Subject Matter

Claims 101 and 102 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed November 20, 2001 have been fully considered but they are not persuasive.

Applicant argues that Section 2111.3 of the MPEP states that the phrase "consisting essentially of" is limited to materials that affect the basic a novel characteristics of the claimed invention. However, this phrase is used to include only small amounts of impurities, water, etc. and to preclude all else. Applicant, however, stated that this phrase does not preclude cross-linking agents in the 37 CFR 1.132 declaration filed July 12, 1999. In the present response, however, Applicant argues that the phrase "consisting essentially of" does preclude crosslinking agents, fibrin, and polypeptide because the crosslinking agent is substantially dissipated; see page 15, lines 3-15 of the November 20, 2001 response. Since crosslinking agents are actually necessary for the invention and reacted with the tropoelastin to polymerize it, it is not clear to the Examiner what consisting essentially of is intended to preclude. The crosslinking agents are not totally reacted. Furthermore, the reacted crosslinkers become part of the polymer structure and are not dissipated. For this reason, "consisting essentially of" was interpreted as having the scope of "comprising" because this is the broadest reasonable interpretation.

In response to the traversal of the Gregory (WO) rejection that the 37 CFR 1.131 declaration overcomes the rejection, the Examiner posits that the declaration is insufficient to overcome the rejection for the reasons set forth below; particularly, the declaration fails to show that due diligence was present and that the Applicant had full

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conception and appreciation of the presently claimed invention. Moreover, it states nothing about the activity of the coinventor Andrew Barofsky.

The declaration filed on March 15, 2001 under 37 CFR 1.131 has been considered but is ineffective to overcome the Gregory et al (WO 96/14807) reference.

The evidence submitted is insufficient to establish diligence from a date prior to the date of reduction to practice of the Gregory et al (WO) reference to either a constructive reduction to practice or an actual reduction to practice. Specifically, there is no due diligence shown from the conception date before May 23, 1996 to the constructive reduction on February 7, 1997; see MPEP 715.07(a) which is incorporated herein by reference thereto. In fact, a period of 2 days lacking activity has been held to be fatal; see *In re Mulder* 219 USPQ 189, 193 (Fed. Cir. 1983).

In addition, the declaration provides no clear evidence that the conception of the whole claimed invention was made; see MPEP 715.02 which is incorporated herein by reference. For example, the Exhibit A discloses very little about tropoelastin and fails to set forth the detail present in the claims. In addition, Exhibits B and C, which were provided to show due diligence, fail to disclose anything about tropoelastin. For these reasons, Applicant is respectfully requested to show where each of the limitations of the claimed invention is provided for in the declaration. This is due to the fact that conception of the claimed invention is not adequately shown to the extent that this insufficiency alone renders the declaration defective.

Applicant lists activities performed by the inventors between May 23, 1996 and November 13, 1996 (page 17 of the November 20, 2001 response). However, even this

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bulleted list has two inactivity gaps of 2 ½ to 3 months. No reason is given for these delays such that they could be excused. Since inactivity for 2 days and less than a month have been found fatal, the Examiner concludes that the present affidavit is fatally defective also (see MPEP 715.07(a) and 2138.06).

In response to the traversal of the rejection of claims 47 and 48 based upon Applicant's admission, the Examiner maintains that the Applicant's admission in the specification is sufficient to read on the claimed invention such that the present claims are anticipated thereby. On lines 15 to 17, it states that elastin is formed by "the secretion and crosslinking of tropoelastin" in vertebrates. Therefore, the step of forming a biomaterial from tropoelastin is a naturally occurring process upon which the present claims read.

In response to the traversal of Labroo et al, it is noted that claims 47, 48, and 53-55 are limited to "consisting essentially of tropoelastin." Since "consisting essentially of" is indefinite and fails to preclude any particular elements, it is the Examiner's position that the claims are read thereon. In addition, it is noted that the terminology "consisting essentially of" does not preclude any materials because it is not used in a manner consistent with its accepted meaning in present patent law.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned problem is corrected.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 305-3580.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.


Paul Prebilic
Primary Examiner
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